Remarks

Amendment

Claim 28 was amended to correct the "Markush" language of that claim. No change in claim scope was intended or is believed necessary to distinguish the prior art.

Rejections

Claims 1 to 28 of this application were rejected under 35 U.S.C. §§102, 103, and 112. First, claims 1 to 3 were rejected under the judicially created doctrine of obviousness-type double patenting because the examiner believes that the present claims are not patentably distinct from previously issued U.S. patent 6,699,907.

Next, claims 1, 3 to 5, 7 to 10, 12, and 16 to 28 were rejected under 35 U.S.C. §112, first paragraph because the examiner believes that the specification fails to enable a teat dip having C_7 acid or sorbitol.

Claims 1 through 28 were rejected under 35 U.S.C. §102(b) as being anticipated by *Kabara* EP0530861A2 because the examiner believes that: at page 4 thereof, there is a disclosure sorbitol and two or more fatty C_6 to C_{18} acids that are topically applied; there is a sorbitol replacement of 1% to 5%; and that propylene glycol-isopropanol are present with capryl/capric acid at .1% to 5% in example 1. The examiner contends that the concentrations usable are not limited and that one skilled in the art would have known to increase or decrease the amount of the glycol carrier depending on a desired viscosity.

The Invention

The present invention is directed to a method for reducing mastitis using a teat dip for application to bovine teats and/or udders. The method comprises: applying an antimicrobial composition having from about 60% to 95% of a lipophilic polar solvent selected from the group

consisting of propylene glycol, ethylene glycol, glycerol, isopropanol, and sorbitol by weight of composition and at least two C_8 to C_{14} fatty acids in a total amount of from about 0.5% to about 5% by weight of the composition; and being devoid of sufficient fatty acid ester to substantially improve the antimicrobial activity. (Claim 1.)

In another claimed embodiment, there is recited a method for reducing the incidence of mastitis in a dairy animal by applying an antimicrobial composition having from about 50% to about 99% of a lipophilic polar solvent selected from the group recited above, and a C_8 to C_{14} fatty acid in the amount recited above and devoid of an active amount of fatty acid ester. (Claim 4.)

Another such method includes applying an antimicrobial composition having a lipophilic polar solvent having a dielectric constant of greater than 25 a C_8 to C_{14} fatty acid in the above-recited concentration, and being devoid of a substantial amount of fatty acid ester.

Claims 16 to 28 all recite antimicrobial compositions having at least one C_7 to C_{14} fatty acid, and a lipophilic polar solvent having a dielectric constant greater than 25. These compositions may require a second fatty acid in the C_7 to C_{14} range to be present and devoid of an active amount of fatty acid ester. (Claims 16, 18, and 26.)

Response to Rejections

Double Patenting

Regarding the obviousness-type double patenting rejection. Applicants submit herewith a terminal disclaimer related to the earlier-issued U.S. Patent No. 6,699,907.

Enablement – 35 U.S.C. §112

With respect to the rejection under 35 U.S.C. §112 for a lack of enablement regarding C_7 fatty acid and sorbitol, Applicants note that while not expressly disclosed as an inventive feature,

one skilled in the art could arrive at the claimed teaching without undue experimentation based on the teachings of the specification. "That some experimentation is necessary does not preclude enablement; the amount of experimentation, however, must not be unduly extensive." *Atlas Powder Co. v. E.I. du Pont de Nemours & Co.*, 750 F.2d 1569, 1576, 224 USPQ 409, 413 (Fed. Cir. 1984).

Here, the specification recites C_8 to C_{14} fatty acids for use in an antimicrobial composition, for a total of seven fatty acids. Adding one more fatty acid species to the list would not require undue experimentation because only one additional experiment would be necessary to test the antimicrobial activity of the claimed composition. Further, nothing in the specification indicates that C_7 fatty acids should *not* be used. Indeed, the teachings clearly suggest that C_7 fatty acids could be used without any experimentation at all.

For example, one skilled in the art would learn from the specification that C_7 fatty acids could indeed be used in the method of applying a teat dip composition. At page 4, line 8 of the specification, C_6 to C_{14} "short to medium-chain fatty acids" were identified as having antimicrobial and germicidal activities. C_6 to C_{12} fatty acids are also identified at page 5, lines 7 and 8 as possibly assisting the action of the hydrotrope by helping solublize longer fatty acid species in water to improve antimicrobial efficacy. Thus, one skilled in the art would have learned from the specification that C_6 and C_7 fatty acids demonstrated antimicrobial and germicidal activities, and that they may assist in solubilizing longer species of fatty acids in water. Certainly, these disclosures would have suggested to one skilled in the art to conduct an experiment a C_7 fatty acid to reduce the incidence of mastitis in cows.

The present application does not limit the range of fatty acids to the C_8 to C_{14} species. It simply refers to C_8 to C_{14} as the "preferred" range. (See p. 7, lines 4, 5, and 23.) The

formulations specified are also referred to as "preferred embodiments" at p. 8, line 5. Thus, no teaching in the specification renders a fatty acid that is shorter than C_8 as being outside the scope of the invention.

In addition, five examples are disclosed in the specification for testing the compositions to be used in the methods claimed herein. In each example, detailed formulations are provided, and test results on various bacteria are provided for one skilled in the art to emulate for testing with a C_7 fatty acid. Thus, no undue testing or guesswork regarding experimental protocol would have been necessary. The examiner's contention that the claimed ranges of fatty acid species was not enabled by the specification is therefore, traversed, and the rejection under 35 U.S.C. §112 should be withdrawn.

Similarly, the examiner's rejection of claims including sorbitol is traversed because sorbitol would have been known as providing the synergistic effect of being an effective antimicrobial when used with fatty acids as recited in the claims. Sorbitol has a dielectric constant of 33.5, which is above the claimed range of 25. At pages 25 and 26 of the specification, dielectric constants were used to compare solvents having lower dielectric constants such as corn oil and mineral oil. When used with short to medium chained fatty acids the oils with small dielectric constants did not have the efficacy of compositions with solvents having higher dielectric constants. Thus, one skilled in the art would have known to select solvents having higher dielectric constants to achieve the same or similar results as the preferred compositions specifically disclosed in the specification. Since sorbitol has a high dielectric constant of 33.5, it would have been selected by one skilled in the art without undue experimentation.

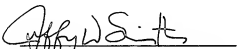
Novelty – 35 U.S.C. §102(b)

The examiner's contention that all claims are anticipated by EP0530861A2 is respectfully traversed because that reference discloses an antimicrobial that *requires* the presence of a fatty acid ester. The claims of the present application expressly omit any ester that is present in an amount sufficient to improve the antimicrobial effect of the composition used in the method. Thus, there is no element-by-element correlation between the cited reference and the claims in this application and no anticipation of the claims. Applicants respectfully request that the anticipation rejection be withdrawn and that this case be passed to issue.

Conclusion

For the foregoing reasons, Applicants respectfully submit that the rejections in the official action have been traversed and request that this case be passed to issue.

Respectfully submitted,



Jeffry W. Smith, Reg. No. 33455
Attorney for Applicant
SMITH LAW OFFICE
440 Science Drive, Suite 302
Madison, WI 53711
(608) 663-8200